

## Shareholder Update | December 2008

The Board wishes to update shareholders on the technical and commercial progress of the Company. OBJ has achieved or initiated several notable initiatives since the September 2008 update including the execution of a Research Collaboration Agreement with a global FMCG company, the execution of a License Option Agreement for the BreatheAssist™ technology and the engagement of several industry experts to assist OBJ to advance its technology POC program.

### UPDATE HIGHLIGHTS

- **DIRECTORS' MESSAGE**
- **TECHNOLOGY POC PROGRAM UPDATE**
- **INDEPENDENT EXPERT REVIEW**
- **RESEARCH COLLABORATION AGREEMENT FOR US\$335,000**
- **COSMETIC TESTING PROGRAM**
- **OBJ LICENSE OPTION AGREEMENT FOR BREATHEASSIST™**
- **RIGHTS ISSUE TO RAISE A\$788,512**
- **GENERAL MEETING OF MEMBERS**

### DIRECTORS' MESSAGE

The Board remains focused on advancing the development of its existing transdermal delivery technologies in collaboration with international experts. The recently executed research collaboration agreement with a global FMCG company is a strong indication of the level of interest in the OBJ transdermal technologies and the potential for commercial outcomes. The Company is also progressing collaboration opportunities to develop cosmetic patch products with the possibility for early revenues. The Company has received commercial interest in the ETP cosmetic patch from a cosmetic ingredient manufacturer that may lead to commercial outcomes upon successful demonstration of cosmetic benefits.

Due to the current challenging economic conditions, the OBJ Board conducted a strategic review and implemented an initiative to secure new business opportunities with the potential for near-term cashflow. The BreatheAssist™ License is consistent with OBJ's strategic objective to broaden and strengthen its technology and/or product portfolio. Importantly, the acquisition/license provides the opportunity to enhance shareholder value with intended near-term cashflow dilation and filtration products and a future nasal drug delivery pipeline. The nasal dilator technology is complementary to OBJ's existing transdermal delivery technologies, enabling integration with the Company's existing capabilities and management resources. Additionally, there are planned changes to the Board structure under the proposed License Agreement with the addition of Rod Tomlinson and a second independent director that will strengthen its pharmaceutical networks, commercial and drug delivery capabilities.

This Shareholder Update provides an overview of the status and achievements of the Company since the September update. The Company has advanced its technology POC program, executed a Research Collaboration Agreement with a global FMCG company, executed a License Option Agreement for BreatheAssist™ and initiated a Rights Issue to ensure that the Company is adequately funded going into 2009. The Board wishes to thank shareholders

For personal use only

for their continued support despite the difficult trading conditions. The Directors are fully cognisant of the opportunities and issues facing the Company, and are committed to implementing strategic initiatives and exploring new business opportunities to restore shareholder value.

---

**TECHNOLOGY  
PROOF-OF-  
CONCEPT (POC)  
PROGRAM**

In September 2008 the Company released a shareholder update advising that the *in vitro* proof-of-concept (POC) program conducted at the University of Queensland (UQ) under the supervision of Professor Michael Roberts to validate the OBJ technology had found initial evidence supporting enhanced transdermal delivery of Naltrexone by the Dermaportation (DP) platform. However, the improvement in *in vitro* drug diffusion was less than results previously achieved at Curtin University of Technology (Curtin) under the supervision of Associate Professor Heather Benson.

An objective of the POC program was to validate previous *in vitro* skin diffusion studies that had been conducted at Curtin showing preliminary evidence that magnetic delivery increased the transdermal delivery rate and amount of hydrophilic small molecules and peptides. Due to the variability in results between laboratories, the Company subsequently initiated a broader proof-of-concept program to attempt to identify and optimise the key technology, equipment and skin model factors that may have contributed to these variable results

Follow-up studies conducted by OBJ to review the effect of technology and equipment factors continued to show variable results. OBJ subsequently engaged third party consultants to perform an independent review of the technology and skin diffusion results (see Independent Expert Review below). Following recommendations by the independent reviewers, OBJ initiated a mechanistic study program to investigate and optimise the skin effect of the proprietary DP and Enhanced Transdermal Polymer (ETP) magnetic fields using a non-drug test model. Preliminary results suggest that changing the magnetic field parameters may reduce skin impedance which is expected to improve drug diffusion.

This mechanistic model and improvements to the study design will now be used by the Company to optimise the technology and improve the reliability and repeatability of DP and ETP enhanced drug diffusion.

---

**INDEPENDENT  
EXPERT REVIEW**

OBJ engaged independent transdermal experts to review the Company's technology, skin diffusion results and POC program, and provide recommendations to further evaluate, optimize and validate the DP and ETP technologies for transdermal drug delivery.

The experts included Professor Brian Barry of Bradford University, Dr Keith Brain of Cardiff University and An-eX Ltd, and Professor Michael Roberts of University of Queensland. The experts were provided with a technical and data package comprising (1) a technical overview of the DP and ETP technologies, (2) skin diffusion study reports and data from Curtin University, (3) skin diffusion study reports and data from University of Queensland, and (4) skin diffusion study reports and data from OBJ.

Professor Brian Barry states that "for a given body site compared between different donors, *in vitro* inter-sample deviations lead to coefficients of variation of about 70% for permeation parameters. The intra-sample variation of a single donor is of the order of 40%. Thus, one can expect marked variation between results of permeation tests done using different skin samples and even within samples."



The reviewers concluded that there was some evidence of damage to epidermal membranes in some of the earlier skin diffusion studies which may have contributed to variability in the data, but there was evidence of a DP and ETP (although lower) effect for a range of molecules across multiple experiments and donors. However, both Professor Barry and Dr Brain concluded that the variability in the data was largely due to inter-donor variability in skin permeation.

The experts provided a number of recommendations related to selection of skin donors and replicates, skin preparation and assessment, study design, drug dose and formulation that will be implemented in future studies in the technology POC program to improve the reliability and repeatability of results. All reviewers recommended that future studies were carried out using (1) dermatomed skin to eliminate potential damage caused by heat separation in epidermal membranes, and (2) AC resistance testing to evaluate skin integrity.

Importantly, the reviewers concluded that there was evidence of a DP effect across some drug molecules and that the method was potentially most suitable for polar, poorly permeating molecules such as peptides. Additionally, the reviewers provided fundamental recommendations to investigate the mechanism and optimise the skin effect of the technology. As a result of these recommendations and in consultation with the reviewers, OBJ has prioritised a mechanistic study program to investigate and optimise the skin effect of the proprietary DP and ETP magnetic fields. The outcome of this mechanistic program is critical to the success of the current research collaboration agreement with the FMCG company.

OBJ is encouraged by the conclusions and recommendations made by the independent reviewers and is in the process of reviewing and reprioritising the technology POC program in accordance with the recommendations.

### **Expert Profiles**

#### **DR KEITH BRAIN** BPharm PhD | Cardiff University; An-eX Limited

Dr Keith Brain was formerly head of Drug Delivery and is currently a Reader in Advanced Drug Delivery and Pharmaceutical Analysis at Cardiff University. He is also a founder and Director of An-eX Analytical Services Pty Ltd, one of the UK's leading transdermal contract research and development laboratories that provides specialist skin services to the pharmaceutical, cosmetics, chemical and agrochemical industries. Dr Brain has broad expertise across dermal and transdermal drug delivery, including prediction of dermal permeation, formulation development and evaluation, bioequivalence, skin penetration enhancement, claim substantiation and risk assessment. His current research interests include drug delivery and biological interfaces.

#### **EMERITUS PROFESSOR BRIAN BARRY** BSc(Pharm) DSc PhD FRPharmS | Bradford University

Professor Brian Barry was, until his recent retirement, Professor of Pharmaceutical Technology and Head of the Drug Delivery Group at The School of Pharmacy, University of Bradford, UK. Professor Barry is a Fellow of the Royal Pharmaceutical Society of Great Britain, a Chartered Chemist, a Fellow of the Royal Society of Chemistry and a Fellow of the American Association of Pharmaceutical Scientists. He has held previous positions as a Community Pharmacist, Boots Chemist; Industrial Pharmacist, Parke Davis & Co; Lecturer in the Department of Pharmaceutics, University of London; Senior Lecturer in

Pharmaceutical Technology and Reader in Pharmacy, Portsmouth Polytechnic; Visiting Scientist at the Institute of Pharmaceutical Science, Syntex Research, and; Dean of the Faculty of Natural and Applied Sciences, University of Bradford. Professor Barry is an international authority on drug delivery systems, specialising in topical and transdermal delivery including transdermal formulation and skin chemistry with some 400 publications. He has previously served as a member of the Chemistry, Pharmacy and Standards Sub-Committee of the Committee on Safety of Medicines. He acts as adviser on topical and transdermal delivery of drugs to the Medicines Control Agency of the UK and the Food and Drug Administration of the USA.

**PROFESSOR MICHAEL ROBERTS** BPharm MSc PhD DSc DipTertEd MBA FAIPM | University of Queensland

Professor Mike Roberts is a registered pharmacist and leading transdermal scientist with over 35 years experience in transdermal drug delivery. He is NHMRC Senior Principal Research Fellow, Professor and Director of the University of Queensland's Therapeutic Research Unit at the Princess Alexandra Hospital. He was previously Professor and Chairman of Pharmacy at Otago University (NZ), and prior to this a community and hospital pharmacist. Dr Roberts has extensive academic and industry experience in the commercialisation of transdermal drug delivery technologies and products. Professor Roberts has published over 350 scientific papers covering aspects of transdermal transport, has co-edited 3 research books and is a regular international speaker in transdermal delivery. He is also Associate Editor of Skin Pharmacology and Applied Physiology; Member of Editorial Board for J Pharmacokinetics and Pharmacodynamics, Pharmaceutical Research, Clinical Pharmacokinetics, Current Drug Delivery, Drug Metabolism & Pharmacokinetics. He was past president of Australasian Pharmaceutical Science Association (APSA) and was a co-recipient of the Inaugural APSA Achievement award "for outstanding achievements in pharmaceutical science" in 2004.

#### RESEARCH COLLABORATION AGREEMENT

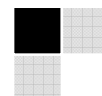
In October 2008, the Company executed a second research collaboration agreement with a global FMCG company to further evaluate and optimise its delivery platforms for an over-the-counter healthcare application. The Company will receive fees of up to US\$335,000 for completion of the project. The agreement also deals with future collaboration and potential licensing rights that may arise if the feasibility project is successful. The feasibility project has commenced and the studies are being conducted by Azopharma Contract Services Inc, a GLP/GMP accredited contract research organisation in the USA.

Importantly, the outcome of the current mechanistic program to optimise the skin effect of the proprietary DP and ETP magnetic fields is critical to the success of this collaboration. Should the technology achieve its success milestones, this project will provide significant industry validation of the OBJ delivery platforms.

This is an exciting development for the Company and the Directors commend management for achieving this initiative.

#### COSMETIC TESTING PROGRAM

The cosmetic patch market is an attractive market for the ETP platforms due to its lower market entry requirements and large market potential. Cosmetic companies are actively seeking novel technologies that can enhance the penetration of active ingredients into the skin and interest has been expressed



in the ETP cosmetic patch.

The Company has initiated a cosmetic study program in technical collaboration with a global cosmetic ingredient manufacturer to validate the efficacy of ETP for cosmetic use. The program aims to determine the effect of ETP delivery on skin morphology for multiple cosmetic active ingredients that are currently used in moisturising, anti-aging and anti-wrinkle applications. The cosmetic ingredient manufacturer is providing OBJ with proprietary cosmetic formulations, clinical and scientific efficacy data and technical support for the program. Should the studies be successful, the cosmetic ingredient manufacturer and a global drug patch manufacturer have expressed potential interest in collaborating with OBJ to develop a cosmetic patch range based on the ETP platform.

### BREATHEASSIST™ LICENSE OPTION

In November 2008, the Company announced that it had executed a Term Sheet for an Option Agreement with ASAP BreatheAssist Pty Ltd ("ASAP") to license or acquire the BreatheAssist™ products and intellectual property rights following a satisfactory due diligence. OBJ has paid a A\$20,000 Option Fee to ASAP and commenced a 60-day due diligence period to evaluate the technology. Upon satisfactory due diligence and exercise of the Option, OBJ and ASAP will complete negotiations of the License Agreement that will grant OBJ exclusive rights to develop and commercialise the BreatheAssist™ products worldwide. The transaction is subject to any required regulatory, statutory and shareholder approval including ASX approval.

ASAP has filed and owns 3 patents (granted US and NZ; accepted Australia) and 7 patent applications covering the method and device of the nasal dilator invention and fragrance and medicament dispensers.

The BreatheAssist™ portfolio offers potential near-term cashflow products with BreatheAssist™ Nasal Dilator and BreatheAssist™ Filtration System, and a potential pipeline of inhalation drug delivery products incorporating the BreatheAssist™ Delivery System.

**BreatheAssist™ Nasal Dilator** is a patented *nasal dilator device* designed to expand the nasal cavity and enhance breathing for the nasal obstruction and snoring markets (see <http://www.digitalfx.com.au/video/BA-draft10-4-07.wmv> for a product demonstration). Studies have indicated that up to 40% of middle aged men and 20% of middle aged women habitually snore.<sup>1</sup> Snoring causes not only social consequences, but has been linked to adverse health outcomes including hypertension, cardio vascular events, daytime sleepiness and accidents.<sup>2</sup>

**BreatheAssist™ Filtration System** is a *proprietary filtration system* that utilizes the dilator device in combination with a specific filter insert (dust/pollution, pollens or antimicrobial) for potential filtration applications. The filtration device provides opportunities to extend the pipeline into potential nasal filtration products.

**BreatheAssist™ Delivery System** is a *proprietary nasal delivery system* that utilizes the dilator device in combination medicated inserts for inhalation delivery of decongestants and other OTC or prescription drugs.

Previous business development activities by ASAP have confirmed significant interest in the BreatheAssist™ products by healthcare companies for potential



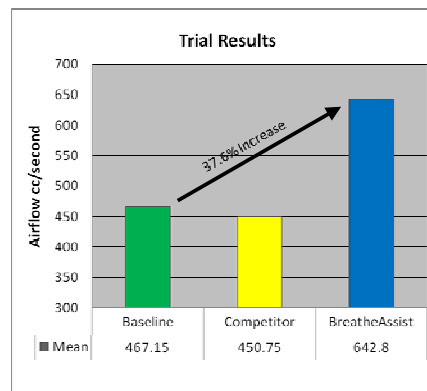
<sup>1</sup> Young T et al. The occurrence of sleep disorder breathing among middle aged adults. N Engl J Med. 1993; 328: 1230-1235

<sup>2</sup> Young T et al. Chronic nasal congestion is a risk factor for snoring. Arch Intern. Med. 2001; 161: 1514-1519

snoring, filtration and delivery applications.

A clinical proof-of-concept (POC) trial conducted at the Royal Victorian Ear and Eye Hospital in Melbourne by Dr Simon Braham in May 2005 demonstrated that BreatheAssist™ Nasal Dilator significantly improved breathing with a **37.6% increase in nasal airflow rates** (175 cc/second increase,  $p < 0.0000$ ) compared to the baseline in normal healthy adults.<sup>3</sup> A leading nasal strip showed no improvement over baseline

( $p < 0.5553$ ). The study used a randomised, cross-over design on 20 healthy human adult volunteers. The investigator concluded that *due to the relationship between improved nasal airflow and reduced snoring, BreatheAssist™ should be effective in increasing airflow and may reduce snoring and improve the quality of sleep in patients with upper airway obstruction.*



## RIGHTS ISSUE

The majority of ASX-listed companies, including OBJ, have been impacted by the current economic downturn and declining share values. It is important during these times that the Company remains focused and adequately funded. The Company has reduced its operating expenditure but requires further capital to continue the development of its technology.

The Rights Issue seeks to **raise approximately \$788,512 by offering 3 new shares for every 10 shares held at an issue price of 0.5 cents per share** plus an Option exercisable at 1.0 cent up to the 31 December 2011 for every one new share issued. The funds raised from the Rights Issue will enable continued technology development and fund working capital requirements for the recently announced new business initiatives. The Rights Issue will open on 16 December 2008 and closes on 2 January 2009.

The Company has executed a mandate with Patersons Securities Limited to undertake the Rights Issue. The Directors appreciate the level of support provided by Patersons at a time when global stock markets are experiencing a significant downturn.

## GENERAL MEETING OF MEMBERS

A Notice convening a General Meeting of Members to be held on 19 January 2009 has been issued by the Company in relation to a requisition by Shareholders pursuant to section 249D of the Corporations Act to consider removal of the incumbent Directors and replacement with new candidates.

The Company has been contacted by BreatheAssist in relation to the section 249D notice lodged on the Company and the subject of the announcement by the Company to ASX on 21 November 2008.

BreatheAssist has informed the Company that the section 249D notice and the potential for changes to the Board of the Company causes concern as to whether the Company will be able to reach agreement with BreatheAssist on the licence agreement.

The Directors of the Company consider the BreatheAssist transaction to be consistent with OBJ's strategic objectives and to have the potential for near

<sup>3</sup> Braham S. ASAP Clinical Trial Report. Melbourne 2005

™ BreatheAssist is a trade mark of ASAP BreatheAssist Pty Ltd

term cashflow products.

The Company is in the process of liaising with BreatheAssist in an attempt to allay their concerns regarding the Company and the section 249D notice.

The Company will provide further updates as discussions with BreatheAssist develop.

**CONTACT  
INFORMATION**

Mr Glyn Denison	Director	<b>P</b> +618 9443 3011
Dr Chris Quirk	Director	<b>E</b> <a href="mailto:info@obj.com.au">info@obj.com.au</a>
Mr Jeff Edwards	Director	<b>W</b> <a href="http://www.obj.com.au">www.obj.com.au</a>

For personal use only

